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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/502,078	07/19/2004	Patrick Wuthrich	SERVIER 426 PCT	2097
25666	7590	06/01/2006	EXAMINER	
THE FIRM OF HUESCHEN AND SAGE SEVENTH FLOOR, KALAMAZOO BUILDING 107 WEST MICHIGAN AVENUE KALAMAZOO, MI 49007			HAWES, PILI ASABI	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 06/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/502,078	Applicant(s) WUTHRICH ET AL.	
	Examiner Pili A. Hawes	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>03-03-2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Summary

The previous office action has been withdrawn. The following is a new grounds of rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 12-17, 19-24 are rejected under 35 U.S.C. 103(a) as being obvious over by Rault et al. US 5672356 in view of Luhn US 6770368.

Rault discloses a rapid release (col. 1, line 10) tablet composition comprising piribedil, maize starch, and lactose (col. 4, lines 5-8). Example 2 discloses the

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composition contains 320 grams piribedil, 278 grams lactose and 80 grams starch. Thus the composition contains 47% piribedil and 52% lactose and starch. The powder obtained is dried (col. 2, lines 60-62) before it is compressed (col. 3, line 4). The reference also teaches the use of lubricants, disintegrants, diluents, and binders (col. 6, lines 45-48).

Rault does not specifically teach the use of co-dried lactose and starch granules.

Luhn teaches using granules consisting of lactose and starch (col. 2, lines 38). The granules exhibit a friability of less than or equal to 80% (col. 2, lines 46-48). The granules in accordance with the invention result in a hardness of greater than 70 N (col. 4, line 9) depending on the ratio of lactose and starch used. If a lower hardness was desired one of ordinary skill in the art would be motivated to modify the ratio of lactose to starch to achieve the desired hardness and it would be obvious to optimize the formulation through routine experimentation to achieve a tablet with the desired hardness. The granules can be used in pharmaceutical preparations (col. 3, line 44).

It would be obvious to one of ordinary skill in the art to make a tablet composition comprising granules consisting of co-dried starch and lactose with piribedil because the use of granules made of co-dried starch and lactose results in good tableting capacity, good flowability, and reduced friability (col. 2, lines 30-35, Luhn). One would further be motivated to combine the teachings of Luhn with Rault because the co-dried granules would improve the rapidly releasing dosage form of Rault.

Response to Arguments

Applicants argue that Rault teaches a bioadhesive composition and thus does not teach a rapid release composition. However, Rault teaches “the invention provides for the rapid release of the active principle (col. 1, lines 10-12). Thus a rapid release tablet composition is at least suggested by the disclosure of Rault.

Claim 18 is rejected under 35 U.S.C. 103(a) as being obvious over by Rault et al. US 5672356 in combination with Dumont et al US 4112093 in view of Luhn US 6770368.

Rault discloses a rapid release (col. 1, line 10) tablet composition comprising piribedil, maize starch, and lactose (col. 4, lines 5-8). Example 2 discloses the composition contains 320 grams piribedil, 278 grams lactose and 80 grams starch. Thus the composition contains 47% piribedil and 52% lactose and starch. The powder obtained is dried (col. 2, lines 60-62) before it is compressed (col. 3, line 4). The reference also teaches the use of lubricants, disintegrants, diluents, and binders (col. 6, lines 45-48).

Rault doesn't teach the use of citric acid in the formulation.

Dumont teaches it is known to add non-toxic pharmaceutically acceptable acids to produce addition salts with organic acids such as citric acid (col. 1, lines 45-55).

Rault does not specifically teach the use of co-dried lactose and starch granules.

Luhn teaches using granules consisting of lactose and starch (col. 2, lines 38). The granules exhibit a friability of less than or equal to 80% (col. 2, lines 46-48). The

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granules in accordance with the invention result in a hardness of greater than 70 N (col. 4, line 9) depending on the ratio of lactose and starch used. If a lower hardness was desired one of ordinary skill in the art would be motivated to modify the ratio of lactose to starch to achieve the desired hardness and it would be obvious to optimize the formulation through routine experimentation to achieve a tablet with the desired hardness. The granules can be used in pharmaceutical preparations (col. 3, line 44).

It would be obvious to one of ordinary skill in the art to make a tablet composition comprising granules consisting of co-dried starch and lactose and citric acid with piribedil because the use of granules made of co-dried starch and lactose results in good tableting capacity, good flowability, and reduced friability (col. 2, lines 30-35, Luhn) and the citric acid produces stabilized acid salts of the pharmaceutical composition. One would further be motivated to combine the teachings of Luhn with Rault because the co-dried granules would improve the rapidly releasing dosage form of Rault.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pili A. Hawes whose telephone number is 571-272-8512. The examiner can normally be reached on 8-4:30 M-F.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

P.A. Hawes
Examiner-1615


Gollamudi S. Kishore, PhD
Primary Examiner
Group 1600